AMENDMENT

In the Claims:

Claim 1 (Original): A method for determining cyclase inhibiting parathyroid hormone (CIP) in a sample comprising:

a) adding to the sample a labeled antibody or antibody fragment specific for a peptide sequence for CIP that presents an epitope available for antibody binding in CIP, but will not bind to this same peptide sequence in cyclase activating parathyroid hormone, in an amount sufficient to bind the CIP present;

b) allowing the labeled antibody to bind to any CIP present, thereby forming a complex; and

c) measuring the amount of labeled complex.

Claim 2 (Original): The method of Claim 1 wherein the labeled CIP antibody or antibody fragment is one of the following, a monoclonal antibody and a polyclonal antibody.

Claim 3 (Original): The method of claim 1 wherein a second antibody is added which is bound to a solid support and specifically binds to a portion of CIP other than that of the labeled antibody, thereby forming a complex.

Claim 4 (Original): The method of Claim 3 wherein the solid support is selected from the group consisting of a protein binding surface, colloidal metal particles, iron oxide particles, latex particles, and polymeric beads.

Claim 5 (Original): The method of Claim 3 wherein the complex precipitates from solution.

Claim 6 (Original): The method of Claim 1 wherein the label or signal generating component is selected from the group consisting of chemiluminescent agents, colorimetric agents, energy transfer agents, enzymes, fluorescent agents, and radioisotopes.

Claim 7 (Currently amended): A method for measuring the amount of cyclase inhibiting parathyroid hormone (CIP) fragment in a sample comprising:

a) adding to the sample a first antibody or antibody fragment specific for a peptide sequence for CIP that presents an epitope available for antibody binding in CIP, but does not bind to this same peptide sequence in cyclase activating (CAP) parathyroid hormone, in an amount sufficient to bind the CIP present;

b) allowing the first antibody to bind to any CIP present, thereby forming a complex;

c) ~~labeling the complex by means of~~ adding a second antibody ~~that has a label or signal generating component attached thereto and~~ that specifically binds to a portion of CIP other than the initial peptide sequence which binds to the first antibody and allowing the second antibody to bind to the complex, wherein said first antibody or said second antibody has a label or signal generating component attached thereto; and

d) measuring this amount of labeled complex.

Claim 8 (Original): The method of Claim 7 wherein the second labeled antibody is added sequentially or simultaneously with the first antibody.

Claim 9 (Original): The method of Claim 7 wherein the first antibody is bound to a solid support.

Claim 10 (Original): The method of Claim 7 wherein the second labeled antibody binds either to the mid-portion of CIP or the C-terminal of CIP and also comprising adding at least a third antibody that specifically binds to an epitope left open after CIP binds to the first antibody and the second antibody, thereby forming a precipitating mass.

Claim 11 (Original): The method of Claim 10 wherein the C-terminal CIP antibody is bound to a solid support.

Claim 12 (Original): A method for measuring cyclase inhibiting parathyroid hormone (CIP) by means of a precipitating or turbidometric immunoassay comprising:

a) adding to the sample a first antibody or antibody fragment specific for a peptide sequence for CIP that presents an epitope available for antibody binding in CIP, but does not bind to this same peptide sequence in cyclase activating parathyroid hormone, in an amount sufficient to bind the CIP present, said antibody being attached to a colloidal particle or moiety which can be used to detect a signal change;

b) allowing the antibody to bind to any CIP present, thereby forming a complex; and

c) measuring the change in signal due to the formation of the complex.

Claim 13 (Original, re-numbered (formerly claim 14)): A substantially pure antibody or antibody fragment sample a labeled antibody or antibody fragment specific for a peptide sequence for cyclase inhibiting parathyroid hormone that comprises an epitope available for antibody binding in CIP, but does not bind to this same peptide sequence in cyclase activating parathyroid hormone.

Claim 14 (Original, re-numbered (formerly claim 15)): The antibody of Claim 14 wherein the antibody is one of the following, a monoclonal and a polyclonal antibody.

Claim 15 (Original, re-numbered (formerly claim 16)): A kit containing reagents for performing an assay for cyclase inhibiting parathyroid hormone (CIP) comprising:

a) a substantially pure antibody or antibody fragment specific for a peptide sequence for CIP that presents an epitope available for antibody binding in CIP, but is not specific for this same peptide sequence in cyclase activating parathyroid hormone; and

b) a labeling component that binds to CIP, but not to the CIP antibody epitope bound by the first antibody.

Claim 16 (Original, re-numbered (formerly claim 17)): The kit of Claim 16 also comprising an antibody specific for the C-terminal portion of CIP.

Claim 17 (Original, re-numbered (formerly claim 18)): A kit containing agents for performing an assay for cyclase inhibiting parathyroid hormone (CIP) comprising:

a) a first substantially pure antibody or antibody fragment specific for a peptide sequence for CIP that presents an epitope available for antibody binding in CIP, but does not bind to this same peptide sequence in cyclase activating parathyroid hormone; and

b) a second antibody that binds to CIP, but not to be the first CIP antibody epitope, which is bound to a solid support.

Claim 18 (Original, re-numbered (formerly claim 19)): The kit of Claim 18 also comprising an antibody specific for the C-terminal portion of CIP.

Claim 19 (New): The method of Claim 11 wherein the solid support is selected from the group consisting of a protein binding surface, colloidal metal particles, iron oxide particles, latex particles, and polymeric beads.

Claim 20 (New): The method of Claim 11 wherein the complex precipitates from solution.

Claim 21 (New): The method of Claim 7 wherein the label or signal generating component is selected from the group consisting of chemiluminescent agents, colorimetric agents, energy transfer agents, enzymes, fluorescent agents, and radioisotopes.

Claim 22 (New): The method of claim 7, wherein the label or signal generating component is attached to the first antibody.

Claim 23 (New) The method of claim 7, wherein the label or signal generating component is attached to the second antibody.

Claim 24 (New): The method of Claim 7 wherein the first antibody or antibody fragment is either of the following, a monoclonal antibody or a polyclonal antibody.

Claim 25 (New): The method of Claim 7 wherein the second antibody or antibody fragment is either of the following, a monoclonal antibody or a polyclonal antibody.

ELECTION OF INVENTION

Claims 1-18 are pending in this application. Claims 19-25 are added herein. Restriction has been required as between the following allegedly distinct groups of inventions:

Group I (claims 1-6): drawn to a method for determining cyclase inhibit parathyroid hormone in a sample, classified in class 435, subclass 7.1;

Group II (claims 7-11; 17-18): drawn to a method for measuring the amount of cyclase inhibiting parathyroid hormone fragment in a sample and a kit, classified in class 435, subclass 7.94;

Group III (claims 12; 15-16): drawn to a method for measuring cyclase inhibiting parathyroid hormone by means of a precipitating or turbidimetric immunoassay, and a kit classified in class 436, subclass 518; and

Group IV (claims 13-14): drawn to a substantially pure antibody or antibody fragment sample, a labeled antibody or antibody fragment specific for a peptide sequence for cyclase inhibiting parathyroid hormone, classified in class 530, subclass 387.1.

Applicants hereby elect Group II (claims 7-11, 17 and 18), with traverse with respect to the restriction between Groups I and II. Applicants expressly reserve their right under 35 U.S.C. § 121 to file a divisional application directed to the nonelected subject matter during the pendency of this application, or an application claiming priority from this application.

DETAILED ACTION

Status of the claims

The claims initially submitted for the application were claims 1-12 and 14 -19. There was no claim 13 submitted. The Office has indicated that Claims 14-19 have been renumbered 13-18, respectively. The Applicants respectfully thank the Office for pointing out this oversight and re-numbering the claims.

Claims 19-25 are added and claim 7 is amended herein. Support for the new claims and the amendment of claim 7 may be found throughout the specification and claims as filed, e.g., at page 5, first full paragraph; page 7, second paragraph; and from page 8, fourth paragraph, to page 9, second paragraph. New claims 19-25 depend directly or indirectly from claim 7 and fall within the gist and scope of the present Group II election. No new matter is added.

Basis for Restriction

In the present restriction, the Office has provided the following as the basis for restriction between Groups I-III:

> Inventions I, II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Invention II requires labeling the complex by means of adding a second antibody that has a label. Invention III requires a colloidal particle which can be used to detect a signal change. While none of the previously mentioned limitations are required for Invention I. Therein restriction is proper.
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> Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the search required for one group is not required for other restriction for examination purposes as indicated is proper.

27 June 2003 Office Action, pages 2-4. The Applicants respectfully traverse.

The subject matter of claims 1 (Group I) and 7 (Group II) are related as combination and subcombination. As such, two-way distinctness and separate classification, status, or field of search must be demonstrated by the office in support of the restriction between claims 1 (Group I) and 7 (Group II). See MPEP §§ 806.05(a)-(c). The Applicants respectfully assert that such distinctness has not been provided. Furthermore, an undue search burden does not appear to be present. For example, the field of search of Group II would include a search of the elements of claim 1 (Group I).

Accordingly, applicants request reconsideration of the restriction requirement, recombination of Group I with elected Group II, and examination of the elected subject matter on the merits.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 532212001500. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

By _____

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